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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,951	09/27/2002	Kaneyoshi Kato	2654 USOP	8949
23115	7590	09/08/2004	EXAMINER	
TAKEDA PHARMACEUTICALS NORTH AMERICA, INC			BERCH, MARK L	
INTELLECTUAL PROPERTY DEPARTMENT			ART UNIT	
475 HALF DAY ROAD			PAPER NUMBER	
SUITE 500			1624	
LINCOLNSHIRE, IL 60069			DATE MAILED: 09/08/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/089,951	Applicant(s) KATO ET AL.	
	Examiner Mark L. Berch	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5,6,8,9,11,13,14,17-20,36 and 38-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,6,8,9,11,13,14,17-20,36 and 38-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/1/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 5, 6, 8, 9, 11, 13, 14, 17-20, 36, and 38-44 are rejected under 35

U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "Diabetes" in claim 42 is ambiguous. It is not a complete term. Diabetes insipidus for example is caused by the inability of the kidneys to conserve water, which is caused by a lack of ADH (central diabetes insipidus) or by failure of the kidneys to respond to ADH (nephrogenic diabetes insipidus). Applicants must select some specific form(s) of diabetes (e.g. Type 2 diabetes mellitus, or Gestational diabetes mellitus; these are metabolic disorders) and they must use that term, and show that one of ordinary skill in the art would have been able to determine that whatever term(s) is/are selected was the one(s) intended.

The spacers Y and Q are not defined. It is not clear what exactly a "main chain" is as opposed to a non-main chain. It is not clear what these atoms are --- can these be atoms such as Se or P or metals? It is unknown what can be attached to the chain (substituents). Applicants point to page 26, lines 11-23, but the definitional part, i.e.

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lines 11-16 provides no additional information other than the fact that the chain is not branched.

Claim 9 is similarly unclear. It has "compring of 1 to 3 groups" It is not clear whether the defective word is composing or comprising. "Comprising" is open-ended and cannot be sued to introduce a Markush group. See MPEP 2173.05(h). Further, the "of" does not make sense after either word. At any rate, it is not clear if the chain in claim 9 can have other groups as well, so long as it has 1-3 of these groups.

The "nitrogen-containing heterocyclic ring" is of unclear scope. Aside from the N of attachment, what other heteroatoms can be present? What is the size of the ring?

Claim 38 is improperly dependent on claim 1, as claim 1 does not provide for such compounds which lack the -Q-Ar group.

Claims 1, 3, 5, 6, 8, 9, 11, 13, 14, 17-20, 36, and 38-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Such non-limited spacer claim language cannot possibly be enabled. Even for Claim 9, this would give a spacer like -O-O-O- or -C(O)-C(O)-C(O)- again, how would these be made?

Claims 1, 3, 5, 6, 8, 9, 11, 13, 14, 17-20, 36, and 38-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a

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way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention..

The method claims appear to be confused. The specification says repeatedly that these compounds inhibit somatostatin receptor binding. See e.g. sentence bridging pages 232-233, and page 7, sentence beginning at line 6. This is reinforced by statements that these compounds are good for diseases associated with somatostatin. See e.g. page 1, lines 7-9, and sentence bridging pages 1-2. On the other hand, original claims 31-32 say that the compounds are somatostatin receptor agonists. This is the exact opposite and is thus contradictory. Thus, new claim 40 refers to agonizing the receptor, but original claim 36 (still pending) refers to inhibiting the receptor. Which is it? The great majority of the references in the specification are to inhibiting the receptor, but there are some to agonizing it. Claim 44 refers to treating diarrhea. A somatostatin agonist would be expected to treat diarrhea; an antagonist would be expected to make it worse. The same is true for diabetes mellitus type 1 and hence diabetic retinopathy. With regard to claim 43, this cannot be deemed enabled even if this matter is resolved. It is true that somatostatin suppresses the release of a variety of GI hormones, including VIP, enteroglucagon and gastrin, and inhibits the release of TSH. But that is quite different from treating e.g. a TSH-producing tumor. So far as the examiner is aware, no such cancers have ever been successfully treated with somatostatin (or a somatostatin antagonist for that matter).

In addition, since the utility in this case is confused, the compound claims are also rejected. Applicants must show that one of ordinary skill in the art would have been able to figure out which of the agonist or antagonist choices was wrong.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on (571)272-0674. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting-SPE of 1624 at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark L. Berch
Primary Examiner
Art Unit 1624

9/2/04